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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PORT-A-CATH® II Implantable Venous Access Systems Preconnected with Polyurethane Catheter

July 8, 1996

I. GENERAL INFORMATION

Applicant's Name and Address:	SIMS Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Lisa Stone Manager, Regulatory Affairs Tel. (612) 628-7224
Common/Usual Name:	Subcutaneously Implanted Intravascular Infusion Port and Catheter
Proprietary Name:	PORT-A-CATH® II Venous Implantable Access Systems Preconnected with Polyurethane Catheter
Equivalence Device Comparison:	PORT-A-CATH® II Venous Implantable Access Systems with Polyurethane Catheter (manufactured by SIMS Deltec, Inc.) PORT-A-CATH® II Dual Lumen Venous Implantable Access Systems Preconnected with Silicone Catheter (manufactured by SIMS Deltec, Inc.)

II. DEVICE DESCRIPTION

PORT-A-CATH® II Venous Systems Preconnected with Polyurethane Catheter are similar in design and function to the current commercially available PORT-A-CATH® II Venous Systems with Polyurethane Catheter.

These systems differ from current commercially available systems in that the portal/catheter connection is made during the manufacturing process, by placing a polyurethane strain relief over the catheter and outlet tubes of the portal.

These systems consist of a standard or low profile portal (titanium/polysulfone) preconnected to a radiopaque catheter (polyurethane) and an access needle. Two catheter options will be available: a 2.6 mm O.D. catheter and a 1.9 mm O.D. catheter. Additionally, systems will be made available with introducer sets.

III. INTENDED USE OF DEVICE

PORT-A-CATH® II Venous Systems Preconnected with Polyurethane Catheter are indicated when a patient requires repeated venous access for injection or infusion therapy and/or venous blood sampling.

IV. DEVICE COMPARISON

	PORT-A-CATH® II Systems Preconnected with Polyurethane Catheter		**PORT-A-CATH® II Dual Lumen Systems Preconnected with Silicone Catheter K955407**	**PORT-A-CATH® II Systems with Polyurethane Catheter K932840 K942024**	
MANUFACTURER	SIMS Deltec, Inc.		SIMS Deltec, Inc.	SIMS Deltec, Inc.	
INDICATIONS FOR USE	A system is indicated when a patient requires repeated venous access for injection (bolus) or infusion therapy and/or venous blood sampling.		A system is indicated when a patient requires repeated venous access for injection (bolus) or infusion therapy and/or venous blood sampling.	A system is indicated when a patient requires repeated venous access for injection (bolus) or infusion therapy and/or venous blood sampling.	
PORTAL DIMENSIONS	*STANDARD*	*LOW-PROFILE*	*DUAL-LUMEN*	*STANDARD*	*LOW-PROFILE*
Height	14.7 mm	11.5 mm	16.0 mm	14.7 mm	11.5 mm
Base	30.5 mm	25.0 mm	50.0 (L) mm x 30.0 (W) mm	30.5 mm	25.0 mm
Septum Diameter	11.4 mm	9.5 mm	11.4 mm	11.4 mm	9.5 mm
MATERIALS					
Portal Housing	Titanium/Polysulfone		Titanium/Polysulfone	Titanium/Polysulfone	
Septum	Silicone		Silicone	Silicone	
Catheter	Polyurethane		Silicone	Polyurethane	
CATHETER DIMENSIONS					
I.D.	1.0 mm	1.6 mm	1.1 mm/1.1 mm	1.0 mm	1.6 mm
O.D.	1.9 mm	2.6 mm	3.4 mm	1.9 mm	2.6 mm
Length	76 cm	76 cm	76 cm	76 cm	76 cm
PORTAL/CATHETER PRECONNECTED	YES		YES	NO	

V. SUMMARY OF STUDIES

A. Functional Testing

In-vitro mechanical testing was conducted according to the "Guidance on 510(k) Submissions for Implanted Infusion Ports," October 1990. Only catheter to portal connection testing was performed, since these preconnected systems are the same as current commercially available systems, except for the connection scheme.

Biocompatibility testing was conducted on all system components.

B. Clinical Studies

Clinical studies were not deemed necessary regarding PORT-A-CATH® II Venous Systems Preconnected with Polyurethane Catheter due to their similarity in materials, design and function to current SIMS Deltec commercially available systems.

C. Conclusions Drawn from the Studies

The results of the testing indicated that PORT-A-CATH® II Venous Systems Preconnected with Polyurethane Catheter function according to specification and the materials used in the system are biocompatible. Therefore, these systems are considered acceptable for human use.